



May 11, 1999 MAY 14 09:20

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

To Whom It May Concern:

This is in response to the request for comments regarding the Federal Register Notice of March 12, 1999 entitled "Draft Guidance for Industry on Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling; Availability" [Docket No. 99D-0254]

This draft guidance for industry represents the Agency's current thinking on proprietary and established name placement, size and prominence in advertising and promotional labeling.

The following represents the collective comments of Warner-Lambert Company, Morris Plains, NJ.

While the Agency has made it clear in the draft guidance that the size of the established name letters should be independent of whether the established name is printed in upper- or lower- case letters, it is still unclear whether or not it would be appropriate to use ascending or descending letters as a guide when determining actual print size. We would like the Agency to consider this issue and determine whether only like-nonascending/nondescending letters should be used when determining the actual print size of the established name letters.

Additionally, with regard to the juxtaposition of the proprietary name and the established name for products with one active ingredient, we would like the Agency to clarify whether or not it would be appropriate to separate the established name from the proprietary name by the dosage strength.

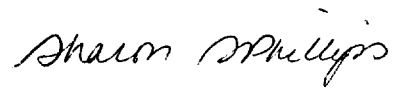
99D-0254

C5

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We appreciate the opportunity to comment on this draft guidance.

Sincerely,

A handwritten signature in cursive script, reading "Sharon S. Phillips".

Sharon S. Phillips
Senior Manager
Advertising and Labeling
Worldwide Regulatory Affairs

FedEx USA Airbill

FedEx
Tracking
Number

810433718555

Form
I.D. No.

0210

SPH11

Recipient's Copy

1 From 
Date **5/13/99**

Sender's Name **Sharon Phillips** Phone **(973) 540-2920**

Company **WARNER LAMBERT CO**

Address **201 TABOR RD**
Dept./Floor/Suite/Room

City **MORRIS PLAINS** State **NJ** ZIP **07950**

2 Your Internal Billing Reference Information **J-002-80-340-009-743**

3 To
Recipient's Name **Dockets Management Branch** Phone **()**
HFA - 305

Company **Food and Drug Administration**

Address **5630 Fishers Lane, Room 1061**
(To "HOLD" at FedEx location, print FedEx address here) Dept./Floor/Suite/Room

City **Rockville** State **MD** ZIP **20852**

For HOLD at FedEx Location check here

☐ **Hold Weekday**
(Not available with
FedEx First Overnight)

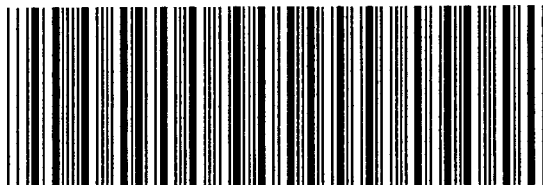
☐ **Hold Saturday** (Not available at all locations)
(Available for FedEx Priority Overnight
and FedEx 2Day only)

For WEEKEND Delivery check here

☐ **Saturday Delivery**
(Available for FedEx Priority
Overnight and FedEx 2Day only)

☐ **NEW Sunday Delivery**
(Available for FedEx
Priority Overnight only)

☐ Check here
if residence
(Extra charge applies
for FedEx Express Saver)



8 1 0 4 3 3 7 1 8 5 5 5

4a Express Package Service Packages under 150 lbs.Delivery commitment may
be later in some areas.

- ☒ **FedEx Priority Overnight**
(Next business morning)
- ☐ **FedEx Standard Overnight**
(Next business afternoon)
- ☐ **FedEx First Overnight**
(Earliest next business morning delivery to select locations) (Higher rates apply)
- ☐ **FedEx 2Day**
(Second business day)
- ☐ **FedEx Express Saver**
(Third business day)
- FedEx Letter Rate not available. Minimum charge: One pound rate.

4b Express Freight Service Packages over 150 lbs.Delivery commitment may
be later in some areas.

- ☐ **FedEx Overnight Freight**
(Next business day)
- ☐ **FedEx 2Day Freight**
(Second business day)
- ☐ **FedEx Express Saver Freight**
(Up to 3 business days)

(Call for delivery schedule. See back for detailed descriptions of freight services.)

5 Packaging

- ☒ **FedEx Letter** (Declared value limit \$500)
- ☐ **FedEx Pak**
- ☐ **FedEx Box**
- ☐ **FedEx Tube**
- ☐ **Other Pkg.**

6 Special Handling

- Does this shipment contain dangerous goods? ☐ No ☐ Yes (As per attached Shipper's Declaration) ☐ Yes (Shipper's Declaration not required)
- ☐ **Dry Ice**
- ☐ **Dry Ice, 9, UN 1845** x kg ☐ **Cargo Aircraft Only**

*Dangerous Goods cannot be shipped in FedEx packaging.

7 Payment

- Bill to:** ☒ **Sender** (Account No. in Section 7 will be billed)
- ☐ **Recipient**
- ☐ **Third Party**
- ☐ **Credit Card**
- ☐ **Cash/Check**
- (Enter FedEx Account No. or Credit Card No. below)



Total Packages	Total Weight	Total Declared Value*	Total Charges
		\$ 00	\$

*When declaring a value higher than \$100 per shipment, you pay an additional charge. See SERVICE CONDITIONS, DECLARED VALUE, AND LIMIT OF LIABILITY section for further information.

Credit Card Auth.

8 Release Signature

Your signature authorizes Federal Express to deliver this shipment without obtaining a signature and agrees to indemnify and hold harmless Federal Express from any resulting claims.

321

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